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Registration Decision RD2016-03

Noviflumuron

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Registration Decision for Noviflumuron

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Noviflumuron Technical Insecticide, Noviflumuron 50% Manufacturing Concentrate and Recruit HD Termite Bait, containing the technical grade active ingredient noviflumuron, to control colonies of subterranean termites to protect structures from termite damage.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-27, *Noviflumuron*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Noviflumuron and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2015-27. This decision is consistent with the proposed registration decision stated in PRD2015-27.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-27, *Noviflumuron* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Noviflumuron?

Noviflumuron is an insect growth regulator that prevents juvenile termites from developing into adults by disrupting chitin synthesis. Chitin is the main component of the termite exoskeleton. Noviflumuron is the active ingredient in the proposed commercial class product, Recruit HD Termite Bait.

Health Considerations

Can Approved Uses of Noviflumuron Affect Human Health?

Recruit HD Termite Bait, containing noviflumuron, is unlikely to affect your health when used according to label directions.

Potential exposure to noviflumuron may occur when handling and installing or monitoring the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient noviflumuron was of low acute toxicity via the oral, dermal and inhalation routes of exposure, was non-irritating to the skin and minimally irritating to the eye, and did not produce an allergic skin reaction. The manufacturing concentrate, Noviflumuron 50% Manufacturing Concentrate, was of low acute toxicity via the oral, dermal and inhalation routes of exposure, was non-irritating to the skin and eyes, and did not produce an allergic skin reaction. The end-use product, Recruit HD Termite Bait, is a solid bait product that contains a very low level of active ingredient. Recruit HD Termite Bait is considered of low acute toxicity via the oral, dermal and inhalation routes of exposure, and is not considered a potential skin or eye irritant, or a skin allergen. These conclusions were based on the physical form of the bait as well as the low acute toxicity of the active ingredient and other ingredients in the product. No acute hazard labelling is required for the technical grade active ingredient, manufacturing concentrate, or end-use product.

Applicant-supplied short-, and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of noviflumuron to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was reduced fertility. There was an indication that the young were more sensitive than the adult animal. The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Non-occupational exposure is not of concern and is considered to be negligible provided that the Recruit HD Termite Bait is used with the Sentricon Colony Elimination System bait station according to label directions.

Occupational Risks From Handling Noviflumuron

Occupational risks are not of concern when Recruit HD Termite Bait is used according to the label directions, which include protective measures.

A risk assessment conducted for Pest Control Officers (PCOs) installing and monitoring Recruit HD Termite Bait in Sentricon Colony Elimination System bait stations indicated that the risk is not of concern when the product is used according to label directions.

PCOs can come in direct contact with noviflumuron on the skin when installing or monitoring Recruit HD Termite Bait. Therefore the label will specify that anyone installing or monitoring Recruit HD Termite Bait must wear a long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and safety glasses.

Environmental Considerations

What Happens When Noviflumuron Is Introduced Into the Environment?

When used according to label directions, noviflumuron does not pose an unacceptable risk to the environment.

Noviflumuron is used in a commercial bait system to protect structures from termite infestations. Very little noviflumuron is expected to reach the environment when it is used as a solid bait station to control termite activity.

Value Considerations

What Is the Value of Recruit HD Termite Bait

Recruit HD Termite Bait represents a new method of controlling termites. Unlike traditional termite control products, it is a bait that results in the elimination of the termite colony rather than individual termites.

Recruit HD Termite Bait uses a combination of bait and the insect growth regulator noviflumuron to control subterranean termite colonies by preventing juveniles from developing into adults after they ingest the product. The use of a bait to control termites represents a new method in managing this pest in Canada. The structural pest control industry has identified a need for baits in termite management programs. Recruit HD Termite Bait targets the colony and results in less insecticide being applied compared to traditional soil treatments for termites.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Recruit HD Termite Bait to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

To avoid direct contact with noviflumuron on the skin during installation and monitoring of Recruit HD Termite Bait, PCOs are required to wear a long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and safety glasses. In addition, Recruit HD Termite Bait can only be installed in Sentricon Colony Elimination System bait stations.

Environment

Due to the limited outdoor use, the risk to environment is expected to be minimal. The labels will contain the standard precautionary statements for protecting the environment

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-27, *Noviflumuron)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.